Inquiring Minds

News and notes from the Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, D.C.

January 2002

The 28th Annual Bailey K. Ashford Research Award

The Department of Clinical Investigation, Walter Reed Army Medical Center, is proud to announce the 28th Annual Bailey K. Ashford Clinical and Laboratory Research Award and Symposium. This year the symposium will be held on 2 May 2002 at 1300 hours in Joel Auditorium.

The BKA award is presented annually to the graduating trainee who has contributed the most significant research during his/her years of training at WRAMC. An award for clinical research, as well as laboratory research, will be made.

Application packets will be available the beginning of February. Any attending staff member assigned to WRAMC or to an integrated GME program may submit nominations. A selection committee determines the award finalists, who are then invited to present their major research findings at the symposium.

An engraved medallion, certificate, and monetary prize are presented to the awardees at the joint NNMC and WRAMC graduation exercise in June. Aposter session will be included as part of the symposium, with an award being presented for the best poster presentation.

This award is named in honor of Colonel Bailey K. Ashford for his work in solving the problem of hookworm induced anemia in Puerto Rico during the early 1900s.

Please contact CPT Ken Capps at (202)782-7823 if you are interested in knowing more about this award or the upcoming symposium.

IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of January, February & March 2002:

CLINICAL INVESTIGATION COMMITTEE (CIC):

08 January	19 February
22 January	05 March
05 February	19 March

HUMAN USE COMMITTEE (HUC):

15 January	26 February
29 January	12 March
12 February	26 March

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC):
14 March

All meetings will begin at 1300 and will be held in the fourth floor conference room, Building 6, WRAMC.

A New Web Based Research Course for WRAMC investigators!

The Department of Clinical Investigation is pleased to announce the addition of a web based research course for WRAMC researchers.

DCI has elected to utilize the Collaborative IRB Training Initiative (CITI) Human Subjects Research Education Module, which is operated and maintained by the University of Miami. The CITI training site consists of various modules that focus on different aspects of bio-ethics and human subjects research. Presentations are developed by nationally recognized experts in the field with specific topics including: Informed Consent; Records-Based Research; Genetics Research; and Research with Investigational Drugs & Devices. In addition, there is a WRAMC specific module that contains an overview of DCI and the protocol process from beginning to completion.

Completion of this web course OR the annual "live" WRAMC Research Course is required for all individuals wishing to serve as a Principal Investigator (PI), an Associate

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Inside This Issue

FAQs Regarding Research Protocol Audits

The Department of Investigation (DCI) frequently conducts periodic audits on approved WRAMC research protocols. This article hopes to clarify any questions/concerns that a principal investigator (PI) may have in reference to research protocol audits.

What is the purpose of auditing a research protocol?
DCI conducts periodic audits in order to ensure "good clinical practice" and to enhance the quality of the research. This is part of the WRAMC procedure for the continuing review process mandated by AR 40-38, Clinical Investigation Program. Audits also serve as an educational tool for the investigator.

What research protocols can be audited and what criteria does DCI use for choosing which protocol to audit?
This audit procedure applies to all protocols approved by the WRAMC Clinical Investigation Committee (CIC) and/or Human Use Committee (HUC). Selection of protocols for auditing is based on the following criteria: (a) high risk or invasive procedure; (b) high volume subject enrollment; (c) adverse events (absence of reporting or unexpected number of events); (d) random selection; (e) identification of significant problems during review of annual reports; and (f) multi-center trials.

As the PI of WRAMC research protocol how will I be notified of an audit?
Once a protocol has been selected for an audit, the principal investigator will be contacted by the Chief, Clinical Studies Service (CSS) or the CSS Auditor and an appointment will be scheduled. The PI will be notified of the pending audit 2-3 weeks in advance and will be provided with an Investigator's Checklist annotating the critical elements required to assist him or her in preparing for the audit.

Who will conduct the audit and what is the format?
The audit will always be conducted by the CSS Auditor and at least one other individual selected from DCI. All of the PI's study records should be made available for auditing purposes. The auditors will review the administrative file and at least 10% or 10 study records and complete the Clinical Studies Checklist for DCI audit by assessing the completeness and adequacy of the required critical elements.

How are the results of my audit reported?
Once the audit has been completed, the auditors will conduct an exit interview with the PI to review the audit findings and clarify any issues that arose during the audit. A formal report of the audit findings is then prepared by DCI to include recommendations/actions for corrective measures as a result of the audit. A copy of the Audit Review Report is submitted to the Human Use Committee. The PI and the Medical Monitor are also provided a copy of the audit report. Follow-up visits are completed as required and/or requested by the Human Use Committee.

As a PI what can I do to make sure that I am prepared for an audit?
To ensure that you are ready for an audit - keep good records, maintain the protocol administrative binder, and make sure that consent forms are completed properly. All documentation should be kept in a secure place. You never know when you may be selected for an audit!

Who is the point of contact for audits?
Eleanor Bicknell at (202)782-7830 or CPT Ken Capps at (202)782-7823.

WRAMC Web Based Research Course (cont from page 1)

Investigator, or a Research Coordinator on a WRAMC research protocol. The course is also encouraged for all personnel involved in research.

To complete the CITI course, see the DCI website at http://www.wramc.amedd.army.mil/departments/dci/. Click on "Research Courses and Registrations", followed by the link to the web course. You must first register for the course and will receive a login and password via e-mail. You will also receive complete instructions on how to access the CITI training site to begin your training. Before you start the course, read the instructions for WRAMC and note which modules you have to complete. Each module has a quiz associated with it. The passing score is 70% and is based on the overall score from all the required modules.

When you have completed the required training on the CITI site (including the WRAMC specific material), complete the Confirmation of Course Completion, print out the page and click on the submit button. The information will be sent to the WRAMC training coordinator, CPT Ken Capps, via e-mail and a certificate of completion will be sent to you.

After you submit a confirmation form to the WRAMC training coordinator, you will be asked to complete a short survey about the course and given the opportunity to apply for 6 CME Credits through the University of Miami CME Office. Print out the CME request form and submit it along with a handling fee of $60 to the UM CME Office.

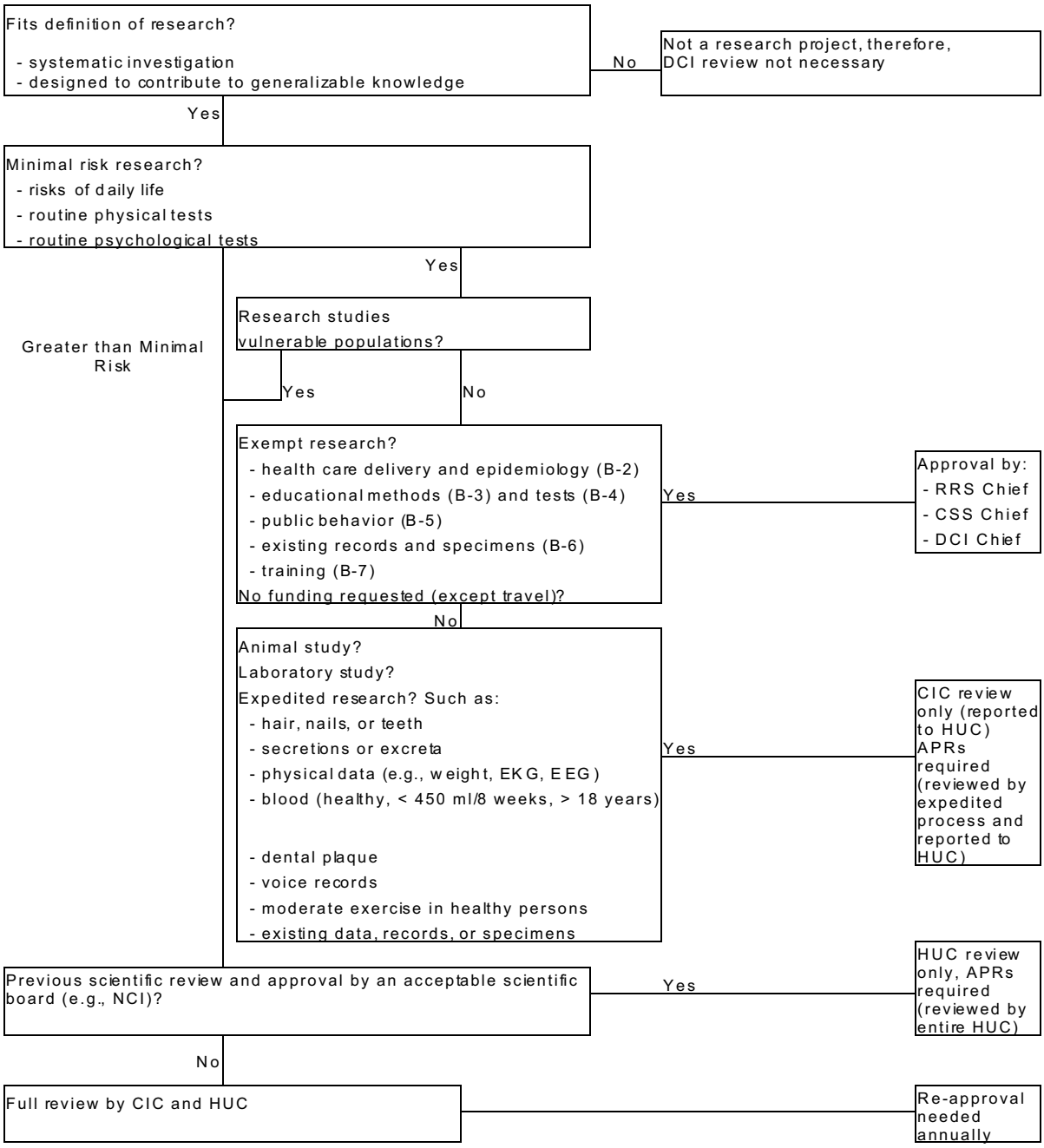
For further information or questions, see the DCI website or contact CPT Ken Capps at (202) 782-7823 or via e-mail at Ken.Capps@na.amedd.army.mil.

DCI Protocol Review and Approval Flow Chart

Ready to start writing your research proposal? Wondering what forms you will need? There are three general categories of research studies: exempt, expedited, and greater than minimal risk. Exempt (low risk) research includes small, retrospective chart reviews and epidemiological surveys and requires approval by DCI staff. Expedited research (observational, minimal risk studies on non-vulnerable populations) includes analyzing EKG readings on healthy military beneficiaries, laboratory studies, animal studies, etc. and requires approval by the Clinical Investigation Committee (CIC). Greater than minimal risk studies (interventional studies) includes trials of new medications or surgical procedures and requires approval by the CIC and the Human Use Committee (HUC).

But exactly what is meant by “minimal risk”? And aren't there other examples of Exempt research that I might qualify for? This is the Flow Chart that the DCI staff uses to determine which review pathway your proposal will fall into. The category will determine which application forms you will need to use. For further information and to download the necessary forms see the DCI website.

DCI Protocol Review and Approval Flow Chart



Note: Extramural and IND/IDE protocols also require approval by CIRO and/or MRMC

Frequently Asked Questions (FAQs) Regarding CRDAs, etc.

Cooperative Research and Development Agreements (CRDAs) have become an essential tool in military medical research. CRDAs are necessary whenever a federal physician (military or civilian) wishes to collaborate scientifically or receive funds from private industry, either directly or through the use of an intermediary.

Here at WRAMC, we have seen an increase in the last couple of years in the amount of research that is being done in cooperation with the private sector, and thus requiring a CRDA. This article answers some common questions investigators have posed regarding CRDAs, etc.

Do I need to do a CRDA for every protocol I write?
No, for protocols that rely solely on intramural resources or federal funds, a CRDA is not needed. But, for protocols that will rely on extramural resources from private industry for the conduction of a study, such as funds for personnel, supplies, equipment, etc, a CRDA is needed.

Why do I need a CRDA?
A protocol application deals with the scientific and ethical aspects of the study. The CRDA is an approved instrument that focuses on the transfer of resources--including salaries for personnel, equipment, supplies, etc.--between the Government (WRAMC) and the private sector.

What should I get approved first, the protocol or the CRDA?
The CRDA and protocol can be submitted at different times. One does not need to be approved first. However, both have to be approved before you can begin your research.

Who can do a CRDA?
CRDAs can be done by one of the research intermediary organizations (HMJF, FACT, TRUE, Geneva, etc.) Their personnel will assemble the pertinent facts of the resource transfer in the proper format and submit the CRDA document (also referred to as a "Statement of Work") to DCI.

What is the approval process for a CRDA?
All proposed CRDAs are submitted by the intermediary (HMJF, TRUE, FACT, Geneva, etc.) to Ms. Daisy Word in the Research Administration Service of DCI. Ms. Word will work with the intermediary to ensure that the CRDA meets all applicable WRAMC requirements. The CRDA is then routed through local approval (DCI and JAG) and is then sent to the Clinical Investigation Regulatory Office (CIRO), who has final authority to approve the CRDA. Following CIRO approval, DCI is notified of the approval. When protocol and CRDA documents are approved, the Research Review Service, DCI generates an approval memorandum for the principal investigator. Only then can work begin on the project.

How long does the approval process take?
Typically, between 60-90 days between submission of CRDA documents to DCI and final notification.

I have an approved CRDA, and I need to hire someone to be paid from it. How do I do this?
Personnel matters on CRDA-supported research are handled by the intermediary (HMJF, TRUE, FACT, Geneva, etc.). They will guide you through this process. Please note, though, that personnel hired through CRDAs become employees of the intermediary; though the investigator may supervise them, they are not federal civilian employees.

A federal civilian employee in my service has put in overtime while working on CRDA-supported research. May I pay him/her overtime pay using CRDA funds?
No, federal civilian employee salary, base salary or overtime, may not be paid using CRDA funds.

I would like to use my CRDA funds to travel. My CRDA does authorize me funds for travel and I am using an intermediary to manage my funds. Does the intermediary do my travel orders?
No, the travel orders may be done by DCI or by your Service. Please keep in mind the guidelines regarding having your travel orders done by DCI, which can be found on the DCI website (TDY.doc). The intermediary will be responsible for issuing a "travel proffer" letter (also known as a Payment of Travel from a Nonfederal Source [PTNS] letter) that will outline which travel expenses will be drawn from your CRDA account. This letter should be sent to Ms. Daisy Word Chief, Research Admin Service, DCI (Bldg 6, Room 4009) who will then arrange for your travel orders as per established WRAMC standard operating procedures for TDY. Alternatively, your service administrator can also arrange for your travel orders.

My CRDA funding allows me up to $5,000 for supplies, but I know I'm going to need more. What should I do?
First, your intermediary will need to contact your sponsor to determine if the extra funding is available. If so, the intermediary submits to DCI an amendment to the CRDA, describing whatever changes are to be made. The amendment has to be approved at both WRAMC and CIRO before it may take effect.

I have a CRDA account with an intermediary, but I am leaving the service. Can I take my funding with me?
No, those funds remain property of the intermediary organization. We advise investigators who are leaving the service (or who are leaving for another duty station) to make the proper arrangements as soon as possible with the intermediary to have another investigator assume responsibility for that account. You are expected to notify DCI under a separate memo of a change in Principal Investigator for that protocol.

I would like to start a multi-center, multi-phase study. Do I need a CRDA for each phase of my protocol (Phase I, Phase II, Phase III)?
The preferred method of handling this issue would be to do a "blanket" or "master" CRDA, which would encompass all phases, or parts, of your protocol. Doing

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Frequently Asked Questions (FAQs) Regarding CRDAs, etc. (From p. 4)

so would require that the intermediary get all financial data from the sponsor up front. These data would then be incorporated into the blanket CRDA. Even though the protocol may be approved by phase, it would be possible to only have to submit one CRDA that would cover all phases of your project.

A drug company has approached me about a project. They have given me an "investigator's agreement" to sign, on behalf of WRAMC, so I can work on their project. Is it OK just to sign the agreement and forgo the CRDA?
No. In any case in which a federal physician, civilian or military, is being asked to represent WRAMC in an agreement with a private company which involves the sharing of resources and/or information between the two parties, appropriate documents must be prepared and signed by representatives of the institution after legal review. A CRDA is straightforward to put together, and can be approved along with the protocol. Usually, a sponsor's "investigator agreement" is designed to function as a CRDA and is provided by sponsors who have no experience in designing a CRDA. Thus, should this situation occur, refer the sponsor to an intermediary who will be happy to assist them.

A drug company has approached me about a project. They have asked me to sign a non-disclosure or confidentiality agreement. Should I sign this document?
No. These agreements are designed to protect the status of any intellectual property that the company may have. Federal employees have no authority to sign these agreements and you would be exposing yourself to substantial personal liability should anything go wrong. Furthermore it is unnecessary to sign these agreements since the Trade Secrets Act, Title 18 United States Code 1905 makes it a felony for Federal personnel to disclose confidential information it receives from a party. Thus, the fact that you are a Federal employee already provides the company with substantial protection beyond that provided by a non-disclosure agreement. In these situations, explain to the company what has been discussed above and refer them to the Office of the Center Judge Advocate (202-782-5800).

Who is the POC for CRDAs at DCI?
Ms. Daisy Word at (202)782-7859 or Daisy.Word@na.amedd.army.mil.

Are there any other funding vehicles besides CRDA's?
Yes. Government grants (NIH, and others) and corporate or individual gifts/donations are examples of other funding vehicles available to investigators. Be aware that grants remain the property of the sponsor. Equipment loans can also be considered as an alternative source of "funding".

How are these other vehicles handled?
We advise that investigators accept equipment on a loan basis as opposed to gifts. This is because loans can be approved locally, where as gifts require approval by MEDCOM. The approval process for gifts can take up to a year. Although monetary gifts can be accepted by WRAMC on behalf of the investigator, we discourage investigators from accepting these because (besides the long approval process) in the past, complex accounting issues and access have created problems and loss of funds. Government grants do not require CRDA's, managed by the research intermediary organizations (HMJF, FACT, TRUE, Geneva, etc.). All issues dealing with access to the grant funds (purchase of supplies, employment of people, etc.) are handled in the same fashion as described for funds under CRDA's. Below you will find a chart that may be helpful in understanding the funding process.

I have completed my project that was funded through a CRDA. There are leftover funds from the project. Can I use them for something else?
No, you cannot. CRDA funding is designed in such a way so that no funds should be left in a CRDA account when the project is complete. Any funds that are left over are

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Flow Sheet

Type	Source	Form	Approval	Approval Time
Equipment	Corporate or Individual	Gift >1-20K	Surg Gen	3-6 Mo
		< 1000	Local	1-2 Mo
		Loan	Local	1-2 Mo
		CRDA	Local & CIRO; admin by a Foundation (i.e.: HMJF)	2-3 Mo
Money	Government	Grant	Local	2-3 Mo
	Corporate or Individual	Grant (CRDA is required)	Local & CIRO; admin by a Foundation	3 Mo
		Gift >1-20K	Surg Gen	3-6 Mo
		<1000	Local	1-2 Mo

DCI Molecular Biology Course for March 2002

The Department of Clinical Investigation is pleased to announce the seventh Molecular Biology Short Course for WRAMC Clinicians (Staff and GME). The course will meet on Wednesday afternoons in March (6, 13, 20, & 27 March) from 1300-1700 in the DCI laboratories.

The goal of this course is to provide clinicians with an improved understanding of common techniques associated with molecular biology to better comprehend the current literature. The format is a 1 hour didactic session followed by a 3 hour, hands on, bench top, wet lab in the DCI laboratories. Participants will perform RNA and DNA extractions, PCR, restriction enzyme digests, DNA sequencing, cloning, HPLC, and many other basic bench top techniques. Each participant will receive a course book with handouts detailing each class session, pertinent articles, and directions for each wet lab. The course will be limited to 12 participants and is free of charge to WRAMC providers.

For further information and to register for this course, see the DCI website or contact Mr. Maged Abdel-Rahim at (202)782-6390 or via Outlook.

Recently Approved Protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols.

Department of Allergy/Immunology

02-33005E: Vaccine Temporally Associated Adverse Events: Review of Clinical Cases Referred To A Tertiary Medical Center
PI: Bryan L. Martin, MC 19 December 2001

Department of Clinical Investigation

02-92007: A Multicenter Double-Blinded Study in Patients with Compensated Cirrhosis Due to Chronic Hepatitis C Who are Non-Responders to Prior Interferon Alfa or Interferon Alfa + Ribavirin
PI: COL Maria Sjogren, MC 14 December 2001

01-92007E: Analysis of Malaria Recombinant Protein Vaccines
PI: David E. Lanar 2 October 2001

Department of Medicine

Cardiology Service

01-12003: ARBITER II: Arterial Biology for the Investigation of the Treatment Effects of Reducing Cholesterol - A Randomized, Placebo-controlled, Double-Blind
PI: LTC Allen J. Taylor, MC 18 October 2001

02-12004: The Effects of Simvastatin on Heart Rate Variability in Dilated Cardiomyopathy
PI: CPT Philip J. Gentlesk, MC 28 November 2001

Endocrine Service

01-13002: Using Telemedicine and Wireless Technology to Improve Diabetic Outcomes in Poorly Controlled Patients
PI: COL Robert A. Vigersky, MC 14 November 2001

01-13004: Pilot Study: Recombinant TSH Stimulation of Radioactive Iodine Uptake in Hyperthyroidism
MAJ Victor J. Bernet, MC 12 October 2001

02-13006: Investigations on Y-Ray-Induced Alterations in Gene Expression Profiles in wt-FRTL-5 and Ret/PTC-3 Oncogene Expressing FRTL-5 Thyroid Cell Lines Utilizing cDNA Expression Array
PI: Yashesh N. Vaishnav, DAC 17 December 2001

Gastroenterology Service

01-14006: B-Catenin Mutations and Nuclear Accumulation are Early Events in Hepatic Carcinogenesis: Role as a Marker to Determine Risk for Hepatocellular Carcinoma in Hepatitis C and Hepatitis B Patients
PI: COL Kent Holtzmuller, MC 15 October 2001

02-14007: The Role of Gastroesophageal Reflux Disease (GERD) in Upper Airway Reactivity Syndrome (UARS)
PI: CPT Brian P. Mulhall, MC 14 November 2001

02-14008E: Utility of colonoscopy in the acute evaluation of lower gastrointestinal hemorrhage
PI: CPT Allan H. Andrews, MC 16 November 2001

02-14007E: *In Vivo* Localization of Glandular Dysplasia in the Esophagus: Identification of differentially expressed molecules in dysplastic Barret's esophagus using archived tissue
PI: MAJ Inku Hwang, MC 26 October 2001

General Medicine Service

02-10004: A Prospective Randomized Trial of Post-Exposure Prophylaxis for Anthrax
PI: COL William Duncan, MC 15 November 2001

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Recent WRAMC publications

Congratulations to the following WRAMC investigators on their recently published papers. This list was compiled from a recent MEDLINE search of the literature. Listed articles have been cleared through DCI and the WRAMC Public Affairs Office. If you have recently published, and we have not included your publication, please let us know so we may list your publication in the next issue of the newsletter.

Abbott KC, Agodoa LY. **Multiple myeloma and light chain-associated nephropathy at end-stage renal disease in the United States: patient characteristics and survival.** *Clin Nephrol.* 2001 Sep;56(3):207-10.

Waselenko JK, Shinn CA, Willis CR, Flinn IW, Grever MR, Byrd JC. **Carboxyamido-triazole (CAI)--a novel "static" signal transduction inhibitor induces apoptosis in human B-cell chronic lymphocytic leukemia cells.** *Leuk Lymphoma.* 2001 Sep-Oct;42(5):1049-53.

Abbott KC, Duran M, Hypolite I, Ko CW, Jones CA, Agodoa LY. **Hospitalizations for bacterial endocarditis after renal transplantation in the United States.** *J Nephrol.* 2001 Sep-Oct; 14(5):353-60.

Tveit DP, Hypolite I, Bucci J, Hshieh P, Cruess D, Agodoa LY, Welch PG, Abbott KC. **Risk factors for hospitalizations resulting from pulmonary embolism after renal transplantation in the United States.** *J Nephrol.* 2001 Sep-Oct;14(5):361-8.

Abbott KC, Hypolite IO, Hshieh P, Cruess D, Agodoa LY, Welch PG, Taylor AJ, Yuan CM. **The impact of renal transplantation on the incidence of congestive heart failure in patients with end-stage renal disease due to diabetes.** *J Nephrol.* 2001 Sep-Oct;14(5):369-76.

Abbott KC, Hypolite I, Welch PG, Agodoa LY**. Human immunodeficiency virus/acquired immunodeficiency syndrome-associated nephropathy at end-stage renal disease in the United States: patient characteristics and survival in the pre highly active antiretroviral therapy era.** *J Nephrol.* 2001 Sep-Oct;14(5):377-83.

Hnatiuk OW, Corcoran PC, Sierra A. **Spirometry in surgery for anterior mediastinal masses.** *Chest.* 2001 Oct;120(4):1152-6.

Richter ER, Shriver CD. **Delayed nephrectomy in grade V renal injury with two interesting anatomic variations.** *Urology*. 2001 Oct;58(4):607.

Kaplan KJ, Goodman ZD, Ishak KG. **Eosinophilic granuloma of the liver: a characteristic lesion with relationship to visceral larva migrans.** *Am J Surg Pathol*. 2001 Oct;25(10):1316-21.

Ales NC, Daniels JT, Frizell ER, Koff JM, Kaplan KJ, Wortmann GW. **Multiple myeloma-associated amyloidosis manifesting as fulminant hepatic failure**. *South Med J.* 2001 Oct;94(10):1036-8.

Borboroglu PG, Amling CL, Schenkman NS, Monga M, Ward JF, Piper NY, Bishoff JT, Kane CJ. **Ureteral Stenting After Ureteroscopy For Distal Ureteral Calculi: A Multi-Institutional Prospective Randomized Controlled Study Assessing Pain, Outcomes and Complications.** *J Urol.* 2001 Nov;166(5):1651-1657.

Brietzke SE, Mair EA. **Injection snoreplasty.** *Otolaryngol Head Neck Surg.* 2001 Nov;125(5):579-80.

McLeod D, Zinner N, Tomera K, Gleason D, Fotheringham N, Campion M, Garnick MB. **A phase 3, multicenter, open-label, randomized study of abarelix versus leuprolide acetate in men with prostate cancer(2)(2).** *Urology.* 2001 Nov;58(5):756-61.

Merseburger AS, Connelly RR, Sun L, Richter E, Moul JW. **SE of serum creatinine to predict pathologic stage and recurrence among radical prostatectomy patients(1).** *Urology*. 2001 Nov;58(5):729-34.

Ellison P, Norwood CW, Turiansky GW. **Off-Center Fold: Chronic Dark-Brown Scales.** *Arch Dermatol.* 2001 Nov;137(11):1521-1526.

Wortmann G, Sweeney C, Houng HS, Aronson N, Stiteler J, Jackson J, Ockenhouse C. **Rapid diagnosis of leishmaniasis by fluorogenic polymerase chain reaction.** *Am J Trop Med Hyg.* 2001 Nov;65(5):583-7.

Klemme WR, Polly Jr DW, Orchowski JR. **Hemivertebral excision for congenital scoliosis in very young children.** *J Pediatr Orthop.* 2001 Nov-Dec;21(6):761-4.

Summers V. **Overshoot effects using Schroeder-phase harmonic maskers in listeners with normal hearing and with hearing impairment.** *Hear Res.* 2001 Dec;162(1-2):1-9.

Abbott KC, Hypolite I, Tveit DJ, Hshieh P, Cruess D, Agodoa LY. **Hospitalizations for fungal infections after initiation of chronic dialysis in the United States.** *Nephron.* 2001 Dec;89(4):426-32.

Bolan CD, Rick ME, Polly DW Jr, DW. **Transfusion Medicine Management for Reconstructive Spinal Repair in a Patient With von Willebrand's Disease and a History of Heavy Surgical Bleeding.** *Spine.* 2001 Dec 1;26(23):

Recently Approved Protocols at WRAMC (cont. from page 6)

Hematology-Oncology Service

01-15007: CALGB 99903: A Phase II Study of Arsenic Trioxide (NSC #706363), IND # 57974) in Urothelial Cancer
PI: CPT Joseph M. Flynn, MC 11 October 2001

01-15009: CALGB 49805: A Phase III Randomized Double Blind Study of Letrozole Versus Placebo in Women with Primary Breast Cancer Completing 5 or More Years of Adjuvant Taxmoxifen
PI: LTC Joseph J. Drabick, MC 11 October 2001

01-16006: A Multicenter, Phase III Randomized Trial for Stage IIIB or IV NSCLC Comparing Weekly Taxol (Paclitaxel) and Carboplatin (Paraplatin) Regimen Versus Standard Taxol and Carboplatin Administered Every Three Weeks, Followed by Weekly Taxol
PI: MAJ Carl Willis, MC 23 October 2001

01-16007: An Open-Label, Multicenter, Randomized, Phase III Study Comparing Oral Topotecan/Cisplatin Versus Etoposide/Cisplatin as Treatment for Chemotherapy-Naïve Patients with Extensive Disease-Small Cell Lung Cancer
PI: MAJ Carl Willis, MC 30 November 2001

Infectious Disease Service

01-19002:Sodium Stibogluconate Treatment of Leishmaniasis
PI: COL Naomi E. Aronson, MC 27 December 2001

Nephrology Service

02-11004: The Effects of Ovarian Steroids on the Responsiveness of mouse Renal Medullary Cells to Vasopressin
PI: CPT Malcolm Gray Napier, MC 6 December 2001

02-11013E: Outcomes with use of ACE inhibitors in dialysis patients
PI: MAJ Fernando Trespalacios, MC 19 December 2001

Pulmonary & Critical Care Medicine Service

01-17003: Quality Management in Sleep Medicine via Telemedicine:Overseas Online Transfer of Polysomnograms via Internet File Transfer Protocol from Landstuhl Germany Army Medical Center to Walter Reed Army Medical Center
PI: LTC David A. Kristo, MC 5 November 2001

01-17007: A Phase IV, Multicenter, Prospective, Open-Label, Observational Study to Evaluate Clinical Practice Patterns of Innohep (Tinzaparin odium Injection) in the Treatment of Acute Symptomatic Deep Venous Thrombosis
PI: MAJ Lisa K. Moores, MC 26 October 2001

01-17014E: Pulmonary findings and their change over time on screening electron beam computed tomography (EBCT)
PI: CPT William Kelly, MC 24 September 2001

Department of Nursing

01-75010: Increasing Testicular Self-Examination in AD Soldiers: An Intervention Study
PI: CPT Carlton G. Brown, AN 17 October 2001

Department of Obstetrics and Gynecology

01-43003: GOG 0184: A Randomized Phase III Study of Tumor Volume Directed Pelvic Plus or Minus Para-Aortic Irradiation Followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for Advanced Endometrial Carcinoma
PI: MAJ Larry G. Maxwell, MC 12 October 2001

01-43005: GOG 0189 - Randomized Phase III Crossover Trial of Chemotherapy (Doxorubicin/Cisplatin/Paclitaxel and G-CSF) VS Hormonal Therapy (Tamoxifen/Megestrol Acetate) in Patients with Stage III & IV or Recurrent Endometrial Cancer
PI: MAJ Larry G. Maxwell, MC 12 October 2001

01-44005: An Observational Trial to Evaluate Tissue and Peripheral Immune Response to HPV 16-Induced Cervical Intraepithelial Neoplasia
PI: LTC Mary F. Parker, MC 3 October 2001

Department of Orthopaedics and Rehabilitation

Physical Medicine and Rehabilitation Service

02-96005: Comparison of Botulinum Toxin Injection for Plantar Fasciitis Vs. Placebo: A Clinical Trial
PI: CPT Mary Sabado Babcock, MC 28 November 2001

01-96009E: The Utility of an Objective Structured Clinical Examination (OSCE) as a Component of competency Assessment of Resident Performance in a Physical Medicine & Rehabilitation Program
PI: CPT(P) Dean Hommer, MC 28 September 2001

Orthopaedic Surgery Service

01-24009: Effects of Alendronate Sodium (FOSAMAX) on Spinal Fusion in the Rabbit Model
PI: CPT Ronald A. Lehman, MC 4 October 2001

01-24010: Biomechanics of Anatomic Versus Straight Forward Technique of Thoracic Pedicle Screw Placement: A Cadaveric Study
PI: CPT Ronald A. Lehman, MC 8 November 2001

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Clinical Research Websites of Interest

Pharmaceutical Information Network (www.pharminfo.com): This site provides pharmaceutical product information with links to research & development, disease information, and discussion groups.

Drug Information Association (www.diahome.org): The DIA provides information on the discovery, development, evaluation, and utilization of medicines and related healthcare technologies.

American Medical Association (www.ama-assn.org): The AMA lots of information regarding health, learning resources, and research.

SciQuest (www.sciquest.com): SciQuest is a technology and solutions company that provides integrated e-commerce and research asset management solutions with links to laboratory supplies and products, as well as scientific information and news.

HumGen (www.humgen.umontreal.ca): The purpose of this web site is to connect visitors to credible and readily accessible policy information on human genetics. This web site consists of different modules such as: GenConnect, which links you to policy making organizations; GenBiblio which allows you to design bibliographies using keywords and jurisdictions; and GenInfo which regularly summarizes new developments.

FDA Information Sheets-IRB Operations and Clinical Investigations (www.fda.gov/oc/oha/IRB/toc.html): Information on IRB makeup, conduct and questions regarding clinical research.

WRAMC October Research Course

DCI presented the WRAMC Research Course on 12 October 2001 in Sanford Auditorium at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, MD. 158 current and potential investigators attended this one-day course.

The objective of this course is to educate WRAMC medical personnel on the ethical issues, current regulations, and design considerations in conducting medical research. Completion of this course is required for Research Coordinators and all individuals wishing to serve as a Principal Investigator (PI) on a WRAMC research protocol. The course is also encouraged for all personnel involved in research including associate investigators, data analysts, etc.

The first speaker was LTC Raul Marin, Assistant Chief of DCI, who gave participants a general overview of DCI and the resources available to investigators. Following a movie entitled: "Evolving Concern-Protection for Human Subjects," was DCI's Corrine Maydonovitch. Ms. Maydonovitch presented the attendees with step-by-step instructions on the submission and review of protocols. Next, LTC Christina Yuan provided attendees with risks and benefits of obtaining informed consent. The morning session ended with the movie: "Balancing Society's Mandates-IRB Review Criteria."

After a lunch break, the program continued with Dr. Eric Marks on tissue banking, followed by the DCI team of Ms. Robin Howard and Dr. Gregory Fant on how to avoid common mistakes when writing and submitting protocols. The next speaker was Dr. Dale Vander Hamm, formerly of the Human Use Review and Regulatory Affairs office in Ft. Detrick, who spoke on the current application of human subject protection regulations. The last two speakers for the day were Mr. Jay Winchester, Senior Counsel for the U.S. Army Medical Research and Material Command, and COL Charles Bolan of WRAIR. They addressed scientific misconduct and publication issues, respectively.

For more information on the WRAMC Research Course and future dates, see the DCI website or call DCI at 782-6389.

Using Current Protocol Templates

DCI would like to request that investigators use the most current version of protocol templates. The templates are updated every 6 months and can be downloaded from the DCI web site. Click on "Download Protocol Templates." Investigators have the option of downloading one specific template or saving all templates on their harddrive. All previous templates on DCI issued floppy disks are invalid. For questions regarding protocol templates, please call DCI at (202) 782-6389.

Frequently Asked Questions (FAQs) Regarding CRDAs, etc. (From p. 5)

not property of the Government, but are property of the intermediary. To this end, we advise that you determine your project length in such a way that you allow ample time for the collection and analysis of data, preparation of publications, and attendance at scientific meetings to present your work.

How does DCI handle intramural funding?
Intramural funding is the money that DCI provides to the investigator to perform his/her research once CIC approves the protocol budget. No intramural funding is granted by DCI when extramural funds exist. Intramural funding is limited to $7,500.00 per year for 2 years for a maximum of $15,000.000 and is subject to availability of funds at the time of request. *For 1-year protocols*: $6,500.00 are for research supplies +/or equipment (no computer equipment) and $1,000.00 for travel. *For 2 year protocols*: $7,500.00 are for research supplies +/or equipment (no computer equipment) for the 1st year, and $6,500.00 for research supplies +/or equipment (no computer equipment) and $1,000.00 travel on 2nd year. No funds will be provided for reprints.

Who are the intermediaries and how can I get in contact with them?
The intermediaries are:
a. Henry M. Jackson Foundation (HMJF): Melinda Harris 301-424-0800 & Norm Gardner 301-294-7289
b. TRUE Foundation: Terri Nakamura 1-888-329-1239
c. Fact Foundation: Peggy Smith 1-800-683-8500
d. Geneva Foundation: Donna Ruttkay 253-383-1398

Recently Approved Protocols at WRAMC (cont. from page 8)

01-24011: The Biomechanical Effects of Various Tapping Techniques with Insertion of Thoracic Pedicle Screws: A Cadaveric Study
PI: LTC Timothy R. Kuklo, MC 8 November 2001

01-24016E: Validation of Software Measurement Tool in Adolescent Scoliosis Patients
PI: LTC David Polly, MC 28 September 2001

02-24017E: Hemimetameric Segmental Shift
PI: Scott B. Shawen, MC 21 December 2001

Department of Pathology and Area Laboratories

01-48001: Use of Robotic Telepathology as an Adjunct to Frozen Section Consultation
PI: CPT Keith J. Kaplan, MC 6 December 2001

Department of Pediatrics

01-65003: Open Label Administration of Human Botulism Immune Globulin
PI: COL Harlan S. Patterson, MC 24 October 2001

Department of Psychiatry

02-72007E: Predicting Psychiatric Readmissions, A Retrospective Analysis
PI: MAJ Dale Levandowski, MC 11 October 2001

02-72008E: Perceived Efficacy by a Consulter About Their Child and Adolescent Psychiatry Consultation
PI: CPT Christopher Lange, MC 26 November 2001

Department of Psychology

01-73002: CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Enlisted Women
PI: LTC Larry C. James, MC 18 October 2001

02-73003E: A Retrospective Analysis of the WRAMC LEAN Project
PI: LTC Larry James, MS 21 December 2001

Department of Radiology

01-4701: A Prospective Study of Outcomes of Patients Examined with Electron Beam Computed Tomography of the Coronary Arteries
PI: Irwin Feuerstein, MD, DAC 18 October 2001

02-47006E: Correlation of magnetic resonance imaging characteristics of the prostate with pathologic findings and clinical outcome: the clinical value of preoperative magnetic resonance imaging in prostate cancer.
PI: MAJ Jong-Ho R. Choi, MC 13 December 2001

Department of Surgery

Anesthesia-Operative Service

01-20002A: Comparison of One-Needle Versus Multiple-Needle Technique for Lumbar Medial Branch Block
PI: LTC Steven P. Cohen, MC 12 October 2001

01-31000E: Effects of Discogenic Pain and Radiculopathy on the Specificity of Lumbar Medial Branch Blocks
PI: LTC Steven Cohen, MC 28 September 2001

01-31001E: Effects of Needle Insertion Site on Discography Results
PI: LTC Steven Cohen, MC 28 September 2001

(Continued on page 11)

DCI Offers a New Course for Researchers!

The Department of Clinical Investigation is proud to announce the "Research In Clinical Medicine: Basic Concepts Approach" course for military and civilian clinician researchers (and aspiring researchers) at Walter Reed Army Medical Center.

This is a three-part series of workshops that provides clinical investigators with the opportunity to learn and apply the principles of good research design in the development of a research proposal. The content of each session is as follows:

Session 1. Ethical studies, the Logic of Research, Science of Medicine
Session 2. Study Design and Critical Appraisal of the Literature
Session 3. Principles of Statistics for Clinical Investigators (a basic concepts approach)

The course is limited to 25 participants and is free of charge to WRAMC personnel. Each participant will receive a course notebook with presentation and workshop notes, pertinent handouts and articles, and a certificate of completion.

The course will meet on 3 consecutive, Thursday afternoons on April 18, April 25, and May 2 from 1330-1600 in Bldg 6 (Borden Pavilion), 4th floor, DCI Conference Room.

For further information or to register, please see the DCI website or contact LTC Raul Marin at (202)782-7840 or E-mail: Raul.Marin@na.amedd.army.mil.

Recently Approved Protocols at WRAMC (cont. from page 10)

Cardiothoracic Surgery Service

02-27000E: Current Trends and Surgical Management of Mediastinal Tumors
PI: MAJ Charles Mulligan,MC 15 November 2001

General Surgery Service

01-20006: Tissue and Blood Library Establishment for Molecular, Biochemical and Histological Study of Breast Disease
PI: LTC Craig D. Shriver, MC 15 October 2001

01-20007: Creation of a Blood Library for the Analysis of Blood for Molecular Changes Associated with Breast Disease and Breast Cancer Development
PI: LTC Craig D. Shriver, MC 15 October 2001

02-31002E: Questionnaire: Selecting a Plastic Surgeon
PI: MAJ Catherine Winslow, MC 5 November 2001

Ophthalmology Service

01-2335-99a: Night Vision Goggle and Night Firing Range Performance After Myopic Excimer Laser Keratorefractive Surgery in U.S. Army Personnel
PI: LTC Kraig S. Bower, MC 2 October 2001

Otolaryngology-Head & Neck Service

01-32005: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Cevimeline in the Treatment of Xerostomia to Radiation Therapy for Cancer in the Head and Neck Region (Protocol 2011A-PRTO003)
PI: LTC John D. Casler, MC 30 November 2001

Urology Service

01-2857-98c: Development of Internet-Accessible Prediction Models for Prostate Cancer Diagnosis, Treatment and Follow-up
PI: COL Judd W. Moul, MC 6 December 2001

02-28007: Mutiservice Laparosocpic Surgical Training in Pigs (Sus scrofa domestica) Using the DaVinci Surgical System
PI: LTC Noah S. Schenkman, MC 13 November 2001

Landstuhl Regional Medical Center

01-80002E: Nerve Fiber Layer Analysis Teleconsultation
PI: LTC Todd D. Hess, MC 6 September 2001

U.S. Army Center for Health Promotion and Preventive Medicine

02-98001E: USACHPPM Dental Mouthguard Study
PI: MAJ Mark Piotrowski, DC 19 December 2001

Walter Reed Army Institute of Research

01-35000E: Field Evaluation of the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE)
PI: MAJ Jose Betancourt , MS 27 September 2001

Attention DCI Employees! Don't Forget Your BMAR!

All DCI personnel must be up to date in their BMAR training. BMAR on-line is available at:

www.cmecourses.com/dod

Your userid & password are the first four letters of your last name and the last five numbers of your SSN. The BMAR course assignments will appear under the **My Course** tab. To take a course, simply click on the course link. To receive credit for a course you must go through the entire course and then take the test at the end. As you complete each course, the course link will be removed from the **My Course** link and added to the **My Transcript** link.

DCI personnel are reminded to print off their evaluation sheets after they complete the training. These sheets certify that you have completed the course.

The online BMAR takes approximately 2½ - 3 hours to complete, with a test at the end to test your knowledge of the covered material.

BMAR is still given didactically. The next didactic versions of BMAR will be given on 09 & 23 January, 06 & 20 February and 06 & 20 March in Joel Auditorium.

The following DCI personnel have birthdays in the months of January, February & March:

COL Maria Sjogren (10 January)
Bader Fileta (10 January)
Timmie Merriwether (31 January)
Susan Barnes (02 February)
CPT Ken Capps (10 February)
Patricia Valente (23 February)
Jana Bednarek (08 March)
Mary Jane Muchui (08 March)
Elmer Jenkins (25 March)

USUHS Schedules Annual Research Day

The Uniformed Services University of the Health Sciences (USUHS) will hold its ninth annual Faculty Senate Research Day & Graduate Student Colloquium 26 and 27 March 2002. This year's theme is " The Postgenomic Era: Implications for Research, Education, and Public Health."

Research Day is held to promote basic science and clinical research collaboration among investigators at USUHS, WRAMC, the National Naval Medical Center, the Naval Medical Research Center, WRAIR, the Armed Forces Radiobiology Research Institute, the Henry M. Jackson Foundation for the Advancement of Military Medicine and other affiliated institutions.

The event seeks to promote research career enhancement and to educate the researcher in such topics as animal use, grants administration, new methodologies, ethics, patent issues, and radiation & lab safety. Research Day also aims to encourage student awareness and involvement in research activities.

The two day event will include invited lectures addressing this year's theme, workshops, and oral & poster presentations by USUHS graduate students and other affiliated institutions. The deadline to submit abstracts for presentations will be announced at a later date.

For more information, see the USUHS-Office of Research website at www.usuhs.mil/resday/index.html.

Inquiring Minds is published quarterly by the Department of Clinical Investigation, WRAMC, as a service to DCI employees and the WRAMC research community.

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Any submissions or questions about content should be directed to CPT Ken Capps at (202) 782-7823.

DCI is SHARPP..
Striving to
Help
All
Researchers from
Planning to
Publication